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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|-------------------------|
| 10/053,462 | 11/08/2001 | Laurence S. Sloman | A01P1083 | 8664 |
| 36802 | 7590 | 04/21/2005 | EXAMINER | |
| PACESETTER, INC. 15900 VALLEY VIEW COURT SYLMAR, CA 91392-9221 | | | | MULLEN, KRISTEN DROESCH |
| ART UNIT | | PAPER NUMBER | | |
| 3762 | | | | |

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/053,462 | SLOMAN, LAURENCE S. |
| | Examiner | Art Unit |
| | Kristen Mullen | 3762 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 24 January 2005 (Response).

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-5,7-10,12-15 and 17-24 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) 1-5,7-10 and 21-24 is/are allowed.

6) Claim(s) 12-15 and 17-24 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 08 November 2001 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Allowable Subject Matter

1. The indicated allowability of claims 12-15 and 17-20 are withdrawn in view of the newly discovered reference(s) to Alt (5,472,453). Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 12-15 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll (6,445,949) in view of Alt (5,472,453).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in

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accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

With respect to claim 12, Kroll shows a method for modifying a detection algorithm comprising receiving one or more signals (VRI) indicative of a patient state; processing the one or more signals (VRI) to determine the patient state (bradycardia, normal sinus rhythm, slow VT, fast VT, or fibrillation); and modifying the detection algorithm (parameters VT1, VT2, VFI) based on the determined patient state (Figs 2, 5A-5C; Col. 5, line 66-Col. 9, line 38). Although Kroll fails to show receiving one or more signals comprises receiving one or more position signals, attention is directed to Alt who teaches receiving one or more position signals. Alt teaches that receiving one or more position signals can be utilized to differentiate between a pathological and physiological tachycardia, and to detect a collapse or loss of consciousness, thereby causing the device to apply a more drastic therapy (Col. 7, lines 11-23, Col. 8, line 28–Col. 9, line 29, Col. 14, lines 9-19, Col. 14, line 53-Col. 15, line 22). Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the method of Kroll to include receiving one or more signals comprising receiving one or more position signals as Alt teaches in order to differentiate between a pathological and physiological tachycardia, and to detect a collapse or loss of consciousness in order to cause the cardiac device to apply a more drastic therapy.

Regarding claims 13 and 14, Kroll shows the receiving one or more signals comprises receiving one or more activity signals (VRI – activity of the heart).

With respect to claims 13 and 14, Alt further shows receiving one or more signals comprises receiving one or more activity signals (Col. 7, lines 11-23, Col. 14, line 53-Col. 15, line 22)

Regarding claim 15, Kroll further shows providing plural sets of parameter values corresponding to various patient states (VT1 and BRI corresponds to a normal sinus rhythm, VT1 and VT2 corresponds to a slow ventricular tachycardia, VT2, and VFI correspond to a fast tachycardia, and VFI corresponds to ventricular fibrillation), and wherein modifying the detection algorithm (steps 318-320, steps 322-324, steps 340-342, 344-346, steps 366-368, steps 368-370-372) further comprises using the corresponding set of parameter values based on the determined patient state (Figs 2, 5A-5C; Col. 5, line 66-Col. 9, line 38).

With respect to claim 17, Kroll shows an implantable cardiac device comprising: a sensor that is operative to generate one or more signals indicative of a patient state (step 206, step 302); and a controller that is in communication with the sensor, the controller being programmed to apply a detection algorithm to received electrical activity signals, wherein the controller is operative to receive the one or more signals from the sensor, process the one or more signals to determine the patient state, and adjust one or more parameter values (steps 318-320, steps 322-324, steps 340-342, 344-346, steps 366-368, steps 368-370-372) of the detection algorithm based on the determined patient state (Figs 2, 5A-5C; Col. 5, line 66-Col.. 9, line 38). Although Kroll fails to show the sensor comprises a position sensor, attention is directed to Alt who teaches a cardiac device comprising a position sensor Alt teaches that a position sensor can be used to help differentiate between a pathological and physiological tachycardia, and to detect a collapse or loss of consciousness, thereby causing the cardiac device to apply a more drastic therapy (Col. 7, lines 11-23, Col. 8, line 28-Col. 9, line 29, Col. 14, lines 9-19, Col. 14, line 53-Col. 15, line

22). Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Kroll to include a position sensor as Alt teaches in order to differentiate between a pathological and physiological tachycardia, and to detect a collapse or loss of consciousness in order to cause the cardiac device to apply a more drastic therapy.

Regarding claims 18 and 19, Kroll shows the sensor comprises an activity sensor (one that measures heart activity).

With respect to claims 18 and 19, Alt further shows the sensor comprises an activity sensor (Col. 7, lines 11-23, Col. 14, line 53-Col. 15, line 22).

Regarding claim 20, Kroll further shows the controller is operative to maintain a plurality of sets of parameter values corresponding to the respective patient states (VT1 and BRI corresponds to a normal sinus rhythm, VT1 and VT2 corresponds to a slow ventricular tachycardia, VT2, and VFI correspond to a fast tachycardia, and VFI corresponds to ventricular fibrillation) and wherein the controller adjusts the detection algorithm by using one of the sets of parameter values based on the detected patient state (Figs 2, 5A-5C; Col. 5, line 66-Col. 9, line 38).

Double Patenting

4. Applicant is advised that should claims 13 and 18 be found allowable, claims 14 and 19 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof, respectively. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Allowable Subject Matter

5. Claims 1-5, 7-10, and 21-24 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

kdm

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